

FIGURE 1

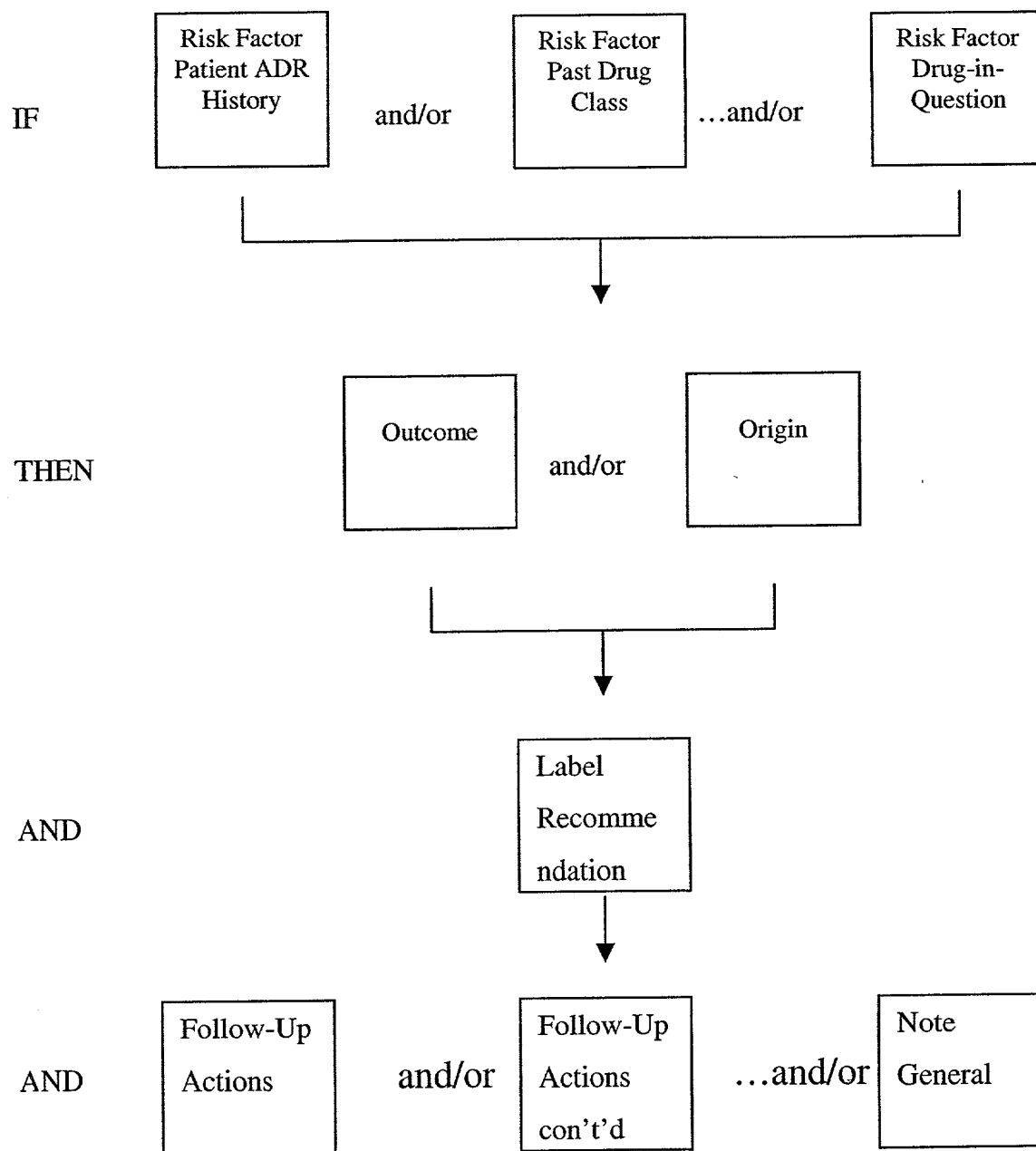


FIGURE 2

Category	Lexical Element	Lexical Element	Lexical Element
Risk factor (RF) patient history			
Risk due to past history			
RF patient ADR history	Sepsis	Hypersensitivity	Hypersensitivity
RF patient family history			
RF patient concurrent condition			
Risk due to current disease			
RF past drug		Enbrel	<Enbrel component>
RF past drug class			
RF concomitant drug			
RF concomitant drug class			
RF drug-in-question (DIQ) class	DMARD	DMARD	DMARD
RF DIQ	Enbrel (etanercept)	Enbrel (etanercept)	Enbrel (etanercept)
RF difference of gender			
RF age			
Outcome	Sepsis	Hypersensitivity	Hypersensitivity
Outcome origin			
Notes on outcome and resolution			
Prescribing action for DIQ	Contraindication	Contraindication	Contraindication
Follow-up actions			
Follow-up actions cont'd			
Conditional follow-up actions			
FUA condition			
FUA conditional action			
Instructions to patient			
Conditional instructions to patient			
ITP condition			
ITP conditional action			
What to remain alert for			
Not to be used as alternate therapy for			
Parameters to monitor			
What to test or check			
When to test or check			
Why/what to consider			
Prescribing notes to Physician			

FIGURE 3

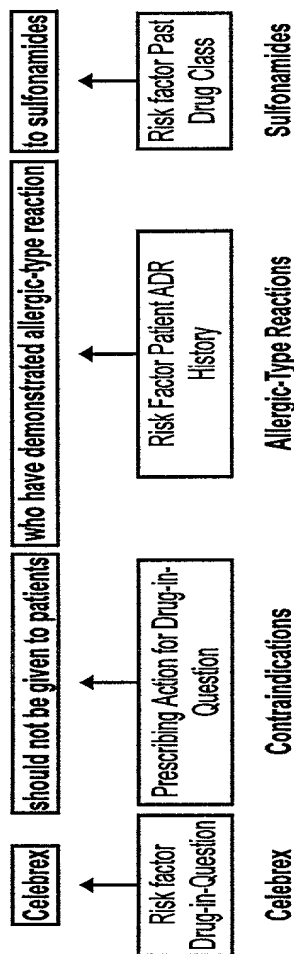
Category	Lexical Element	Lexical Element
Risk factor (RF) patient history		
Risk due to past history		
RF patient ADR history		
RF patient family history		
RF patient concurrent condition		
Risk due to current disease		
RF past drug		
RF past drug class		
RF concomitant drug		
RF concomitant drug class		
RF drug-in-question (DIQ) class	DMARD	DMARD
RF DIQ	Enbrel	Enbrel
RF difference of gender		
RF age		
Outcome	New infection	sepsis
Outcome origin		
Notes on outcome and resolution		
Prescribing action for DIQ	Continue	Discontinue
Follow-up actions	Monitor closely	
Follow-up actions cont'd		
Conditional follow-up actions	Discontinue if new infection becomes serious	
FUA condition		
FUA conditional action		
Instructions to patient		
Conditional instructions to patient		
ITP condition		
ITP conditional action		
What to remain alert for		
Not to be used as alternate therapy for		
Parameters to monitor		
What to test or check		
When to test or check		
Why/what to consider		
Prescribing notes to Physician		

FIGURE 4

Figure 5: Sample of mapping a conditional text statement to a rule structure, using dictionary terms

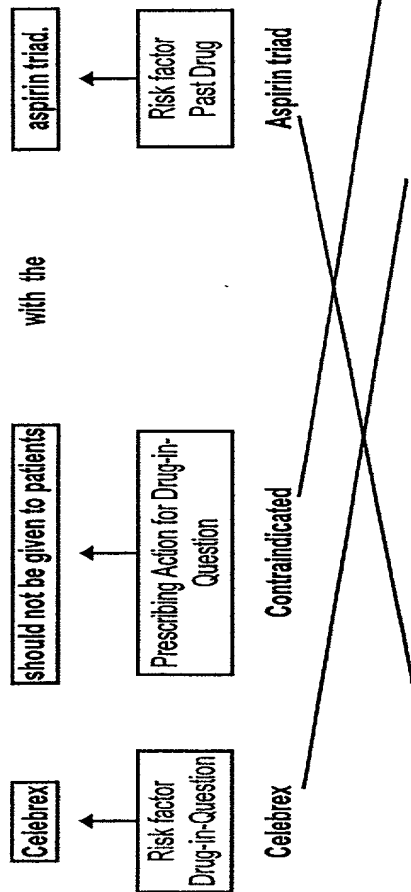
Label Text:

Celebrex should not be given to patients who have demonstrated allergic-type reactions to sulfonamides.			
Risk Category			
Risk Factor Patient past history			
Risk Factor Patient ADR history			Allergic-type reactions
Risk factor Patient family history			
Risk Factor Patient concurrent condition			
Risk factor Past drug			
Risk factor Past Drug Class			Sulfonamides
Risk Factor Concomitant Drug			
Risk Factor Concomitant drug class			
Risk Factor Drug-in-Question Class			
Risk factor Drug-in-Question	Celebrex		
Outcome			
Outcome Origin			
Additional Notes on Outcome and Resolution			
Prescribing Action for Drug-in-Question			Contraindicated
Follow-up Actions			
Follow-up Actions cont'd			
Conditional Follow-up Actions			
FUA Condition			
FUA Conditional action			
Instructions to Patient			
Conditional Instructions to Patient			
ITP Condition			
ITP Conditional action			
What to Remain Alert For			
Not to be used as Alternate Therapy For			
Parameters to Monitor			
What to Test/Check			
When to Test/Check			
Why/What to Consider			
Additional Prescribing Note to Physician			
Note General			



Risk Category	Celebrex			Contraindications			Allergic-Type Reactions			Sulfonamides		
	Risk Factor Patient past history	Risk Factor Patient family history	Risk Factor Patient concurrent condition	Risk Factor Past drug	Risk Factor Past drug Class	Risk Factor Concomitant Drug	Risk Factor Concomitant Drug Class	Risk Factor Drug-in Question Class	Risk Factor Drug-in Question	Outcome	Additional Notes on Outcome and Resolution	Prescribing Action for Drug-in-Question
Follow-up Conditional	FUA Conditional Action	FUA Conditional Action	FUA Conditional Action	Instructions Conditional to Patients	Instructions Conditional to Patients	ITP Conditional action	ITP Conditional action	What to Not to be used as Alternate Alert For Therapy For	Parameters to Monitor Test/Check	What to Test/Check	When to Test/Check	Additional Prescribing Note to General Physician

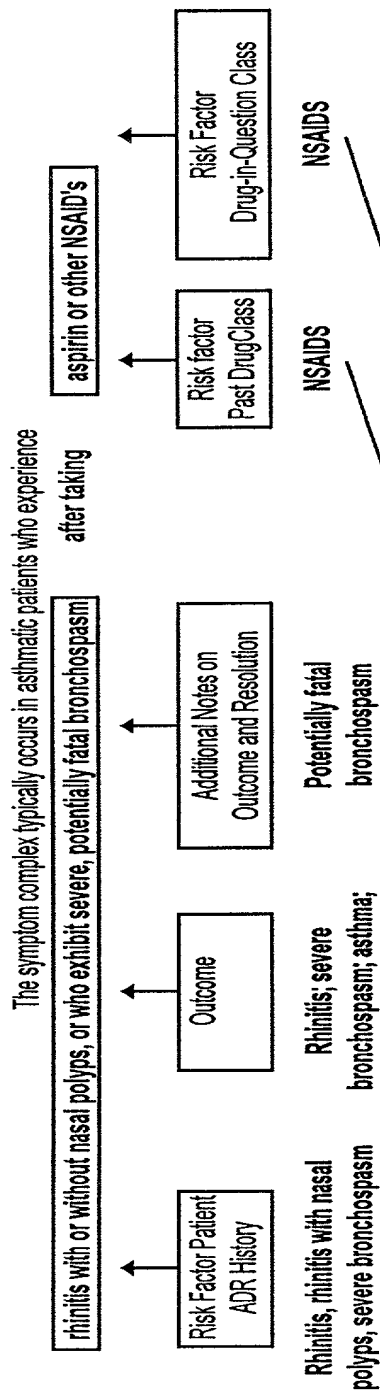
FIG. 7 : Sample of reverse tracing mapping to original



Risk Category	Risk Factor Patient past history	Risk Factor Patient ADR history	Risk Factor Patient family history	Risk Factor Patient concurrent condition	Risk Factor Past drug	Risk Factor Past Drug Class	Risk Factor Concomitant Drug	Risk Factor Concomitant Drug Class	Risk Factor Drug-in Question	Risk Factor Drug-in Question Class	Risk Factor Drug-in Question	Outcome Origin	Additional Notes on Outcome and Resolution	Prescribing Action for Drug-in-Question	Follow-up Actions
Conditional	FUA	FUA	FUA	Instructions Conditional	ITP	ITP	ITP	What to Remain Alert For	Not to be used as Alternate Therapy	Parameters to Monitor	What to Test/Check	When to Test/Check	Why/What to Consider	Additional Prescribing Note to General Physician	
Follow-up	Conditional	Conditional	Conditional	Instructions to Patients	Conditional	Conditional	Conditional								
Cont'd	Actions	Cont'd	Cont'd	Cont'd	Cont'd	Cont'd	Cont'd								

Label text: Celebrex should not be given to patients with the aspirin triad. The symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs. Emergency help should be sought in cases where anaphylactoid reactions occur.

FIG. 8A: Sample of reverse tracing mapping to original label, in three parts



Risk Category	Risk Factor Patient past history	Risk Factor Patient family history	Risk Factor Patient concurrent condition	Risk Factor Past drug	Risk Factor Past Drug Class	Risk Factor Concomitant Drug	Risk Factor Concomitant Drug Class	Risk Factor Drug-in-Question Class	Risk Factor Drug-in-Question	Outcome Origin	Additional Notes on Outcome and Resolution	Additional Prescribing Action for Drug-in-Question
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Follow-up Conditional FUA Conditional Action

Instructions to Patients

Conditional Instructions to Patients

ITP Conditional action

What to Not to be used as Alternate Therapy For

Parameters What to Monitor Test/Check to Consider

Why/What Note to Physician

FIG. 8B

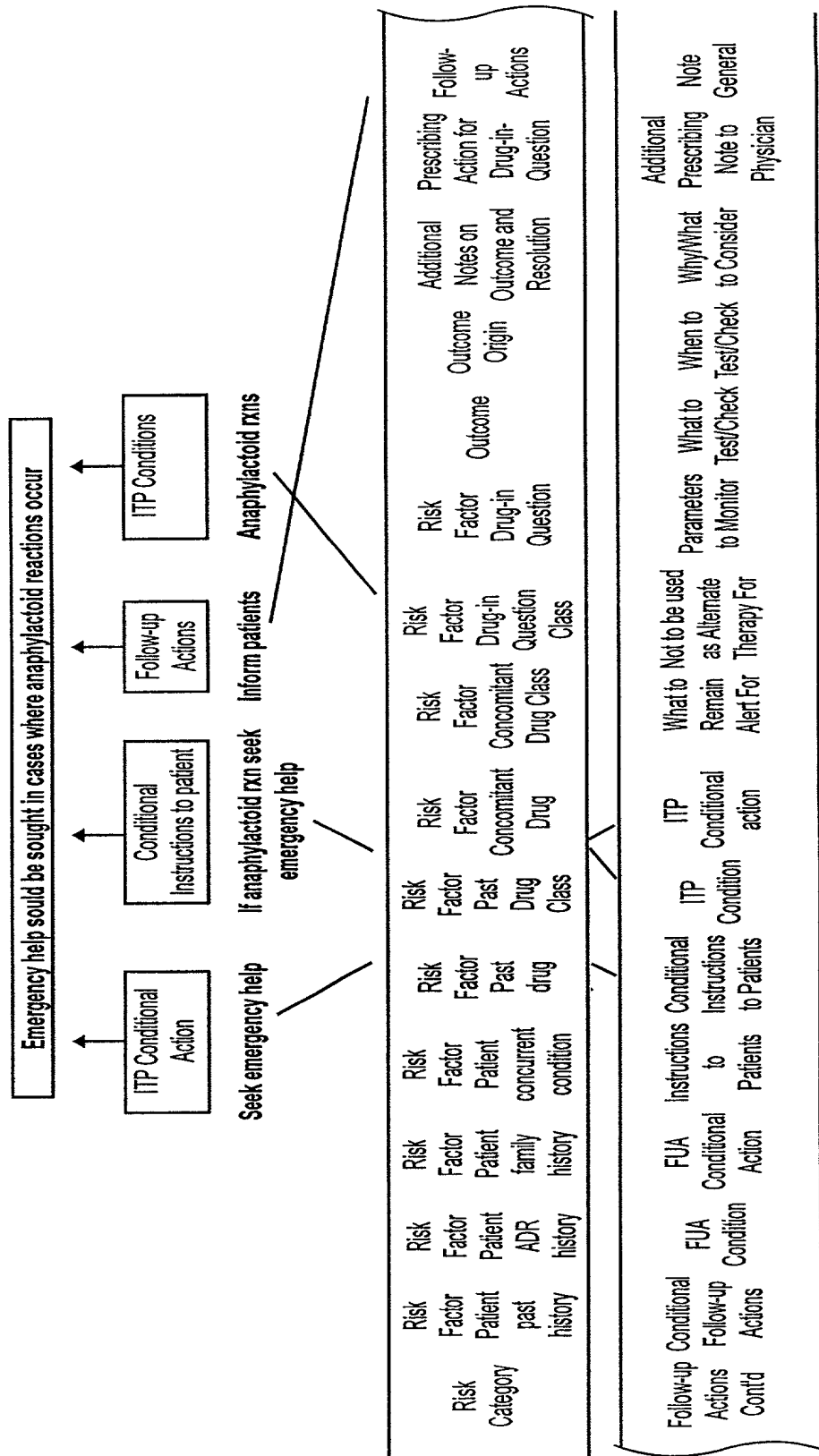


FIG. 8C

DRUG INFORMATION SOURCE 210

INSTANCE OF ADVERSE EVENT CONTENT 220

drug rule 230

drug rule 230

FIGURE 9

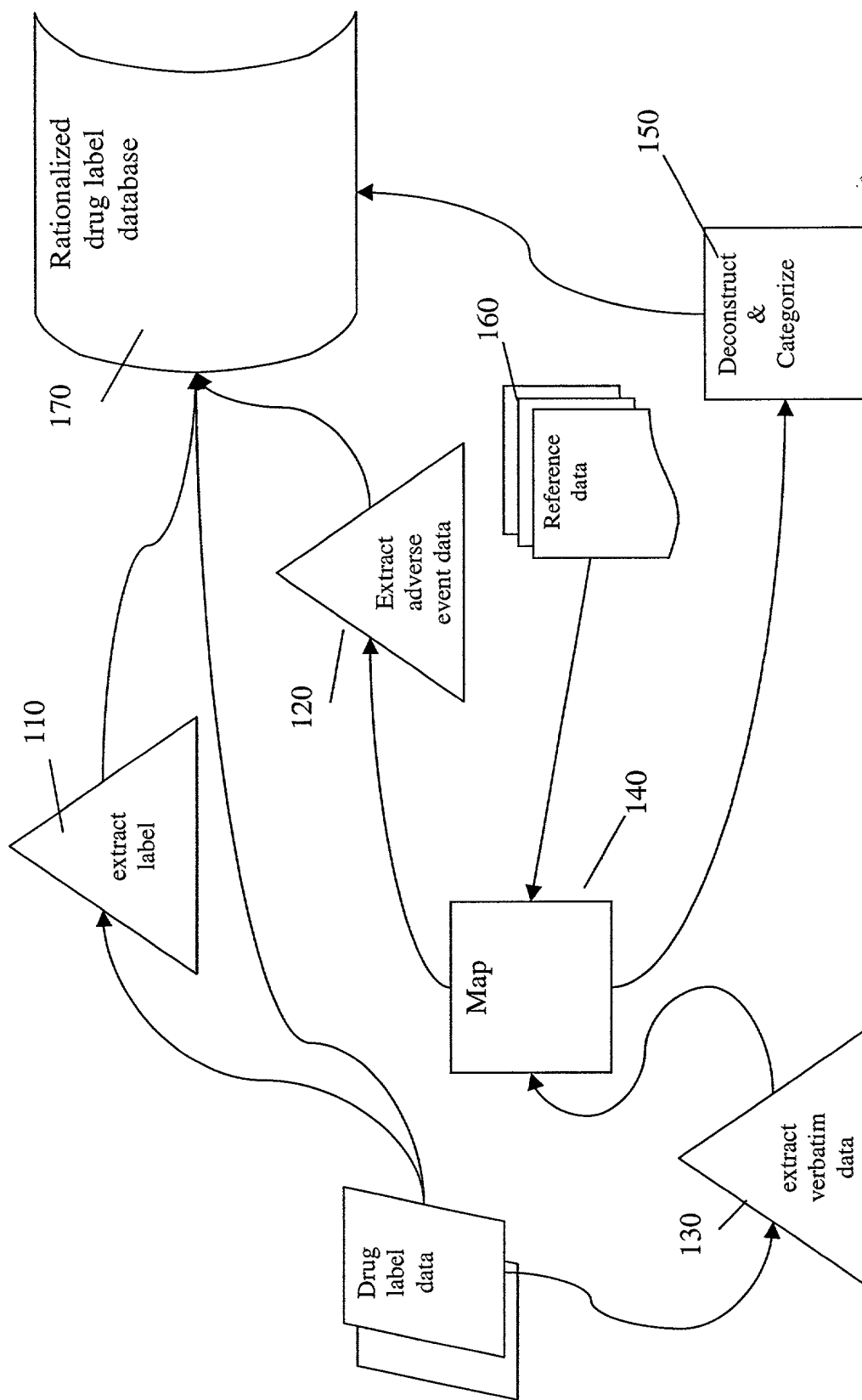


Figure 10